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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/534,387 | 11/22/2005 | Timo Hillebrand | 050372 | 2884 |
| 7590 Buchanan Ingersoll One Oxford Centre 301 Grant St., 20th Floor Pittsburgh, PA 15219 | | 06/15/2007 | EXAMINER STAPLES, MARK | |
| | | | ART UNIT 1637 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/534,387 | Applicant(s) HILLEBRAND ET AL. | |
| | Examiner Mark Staples | Art Unit 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/16/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-40, 44-52, and 57-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-40, 44-52 and 57-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment of claims 35, 38, 51, and 52; the cancellation of claims 1-34, 41-43, and 53-56; and submission of new claims 57-59 in the paper filed on 03/16/2007 is acknowledged.

Claims 35-40, 44-52, and 57-59 are pending and at issue.

Applicants' arguments filed on 03/16/2007 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections and Rejections that are Moot

2. The objection to claim 41 is moot in light of the Applicant's cancellation of this claim.

Claim Rejections Withdrawn - 35 USC § 112 Second Paragraph

3. The rejections of claims 41-43 under 35 USC § 112 Second Paragraph are moot in light of the Applicant's cancellation of these claims.

Claim Rejections Moot - 35 USC § 102

Art Unit: 1637

4. Applicant's arguments with respect to claims 35-40, 44-52, and 57-59 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., qualitative differences between mono- and multivalent cations in their binding effects) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument regarding claims 35, 49, and 52 that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hawkins is not relied upon for teaching silica materials.

In response to applicant's argument that the references, especially Lee et al., fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., non-chaotropic salts) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

Art Unit: 1637

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

New Rejections

Specification

5. The disclosure is objected to because of the following informalities: for using "PCT" in the 3rd sentence of paragraph 036, it appears "PCR" is intended.

Appropriate correction is required.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112 second paragraph

6. Claim 35-47, 49-52, 57, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35-47, 49-52, and 57 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: how the nucleic acid is being removed in step g of claim 35. These claims are indefinite in the removing of the nucleic acid, as no element is recited which would accomplish this.

Claim 36 recites the limitation "said washing buffer" in line 36. There is insufficient antecedent basis for this limitation in the claim.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "monovalent" in claim 59 is used by the claim to mean "divalent", while the accepted meaning is "monovalent." The term is indefinite because the specification does not clearly redefine the term.

New Claim Rejections - 35 USC § 102

7. Applicant has amended base claim 35 and added new claim 58 which recite use of silica and glass materials, necessitating the following new rejections.

8. Claim 35-40, 44-47, 49, 50, 52, 58, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. (US Patent 6,376,194 filed on July 24, 2001).

Regarding claim 35-40, 44-47, 49, 50, and 52, Smith et al. teach a method for isolating nucleic acids from a solution by binding to a solid phase comprising the steps of:

a. providing a solution containing at least one nucleic acid (see Examples 14 and 16);

Art Unit: 1637

- b. combining said solution with additives containing the metallic multivalent/divalent cation of 5 mM MgCl_2 and the metallic monovalent cation of 10 NaCl, that is a ratio of 2:1 which is between about 9:1 and to about 1:9 and is a total of 15 mM salt which is between 5 mM and 0.5 M and contain tris-HCl (see Example 14);
- c. combining the solution with ethanol (see step 10 of Example 14);
- d. providing a solid carrier of magnetic silica particles (see step 3 of Example 16);
- e. contacting and binding DNA to the particles (see step 3 of Example 16) and removing said nucleic acid from said carrier using a washing buffer of pH 9.5 consisting of tris-HCl, which is between 5 and 9.5 (see step 4 of Example 16).

Regarding claims 58 and 59, Smith et al. teach a kit (see column 5 line 66) and teach:

an aqueous solution containing containing the metallic multivalent/divalent cation of 5 mM MgCl_2 and the metallic monovalent cation of 10 NaCl and contain tris-HCl for pH adjustment (see Example 14);

the solution comprising ethanol, an alcohol (see step 10 of Example 14);

a solid carrier of magnetic silica particles (see step 3 of Example 16);

a washing buffer of pH 9.5 consisting of tris-HCl, which is between 5 and 9.5 (see step 4 of Example 16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1637

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 51 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. as applied to claim 35 above, and further in view of Seed et al. (1994).

Smith et al. teach as noted above.

Smith et al. do not specifically teach a wash solution with multivalent and monovalent cations and with no alcohol.

Regarding claims 51 and 57, Seed et al. teach a method using a wash solution of between pH 7 to 10 which overlaps the ranges of 5 to 9.5 and 5 to 20 and which comprises both multivalent cations and monovalent cations each at > 0.1 mM which is less than 5 mM and which does not comprise alcohol (see claim 3 and see p. 7, 1st

column; lines 20-23 for use of divalent/multivalent and monovalent cations; and examples 1, 4-8, 11).

Regarding claim 35, it is also noted that Seed et al. teach glass as a solid carrier(p. 3, second column, line 6).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods of Smith et al. by using a wash buffer with both mulit- and mono- valent cations and no alcohol as suggested by Seed et al. with a reasonable expectation of success. The motivation to do so is provided by Seed et al. who teach that a wash buffer can be used to isolate/separate DNA (see claim 3). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

11. No claim is free of the prior art.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1637

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

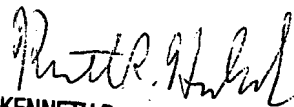
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples
Examiner
Art Unit 1637
June 11, 2007

MS


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER
6/11/07